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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/912,122	07/24/2001	Joshua Makower	TRNSV-015G	4515

7590 10/11/2006

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EXAMINER	
ISABELLA, DAVID J	

ART UNIT	PAPER NUMBER
3738	

DATE MAILED: 10/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/912,122	MAKOWER ET AL.	
	Examiner	Art Unit	
	DAVID J. ISABELLA	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 July 2006*.

2a)☒ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *53-58 and 61-63* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *53-58 and 61-63* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Response to Appeal Brief

Applicant's arguments directed to the rejections to the claims are well presented and, therefore, the finality of that action is withdrawn.

Status of the Claims

Claims 52-58,61-63 are pending for action.

Status of the Claim to Priority

If applicant desires to claim the benefit of a prior-filed application under 35 U.S.C. 119(e) or 120, a specific reference to the prior-filed application in compliance with 37 CFR 1.78(a) must be included in the first sentence(s) of the specification following the title or in an application data sheet. For benefit claims under 35 U.S.C. 120, 121 or 365(c), the reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of the applications.

If the instant application is a utility or plant application filed under 35 U.S.C. 111(a) on or after November 29, 2000, the specific reference must be submitted during the pendency of the application and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior application. If the application is a utility or plant application which entered the national stage from an international application filed on or after November 29, 2000, after compliance with 35 U.S.C. 371, the specific reference must be submitted during the pendency of the application and within the later of four months from the date on which the national stage commenced under 35 U.S.C. 371(b) or (f) or sixteen months from the filing date of the

prior application. See 37 CFR 1.78(a)(2)(ii) and (a)(5)(ii). This time period is not extendable and a failure to submit the reference required by 35 U.S.C. 119(e) and/or 120, where applicable, within this time period is considered a waiver of any benefit of such prior application(s) under 35 U.S.C. 119(e), 120, 121 and 365(c). A benefit claim filed after the required time period may be accepted if it is accompanied by a grantable petition to accept an unintentionally delayed benefit claim under 35 U.S.C. 119(e), 120, 121 and 365(c). The petition must be accompanied by (1) the reference required by 35 U.S.C. 120 or 119(e) and 37 CFR 1.78(a)(2) or (a)(5) to the prior application (unless previously submitted), (2) a surcharge under 37 CFR 1.17(t), and (3) a statement that the entire delay between the date the claim was due under 37 CFR 1.78(a)(2) or (a)(5) and the date the claim was filed was unintentional. The Director may require additional information where there is a question whether the delay was unintentional. The petition should be addressed to: Mail Stop Petition, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

If the reference to the prior application was previously submitted within the time period set forth in 37 CFR 1.78(a), but not in the first sentence(s) of the specification or an application data sheet (ADS) as required by 37 CFR 1.78(a) (e.g., if the reference was submitted in an oath or declaration or the application transmittal letter), and the information concerning the benefit claim was recognized by the Office as shown by its inclusion on the first filing receipt, the petition under 37 CFR 1.78(a) and the surcharge under 37 CFR 1.17(t) are not required. Applicant is still required to submit the reference

in compliance with 37 CFR 1.78(a) by filing an amendment to the first sentence(s) of the specification or an ADS. See MPEP § 201.11.

Response to Arguments

Applicant's arguments filed 7/24/2006 have been fully considered but they are not persuasive. Applicant contention that Lary et al is not prior art is not correct. Applicant has not met the requirements under 37 USC 1.78(a). Accordingly, Lary et al is still a proper reference under 35 USC 102.

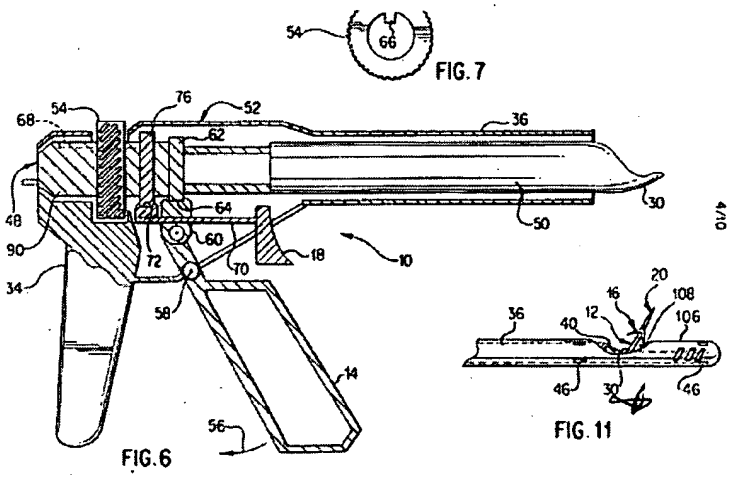
Applicant respectfully traverses the anticipation rejection over Lary et al. on grounds that Lary et al. is not prior art to claim 53. The Examiner will note that this application claims priority to several copending applications. Each of those copending applications claims priority to, and expressly incorporates by reference, two provisional applications that were filed prior to the October 3, 1996 filing date ofLary et al. Namely, those provisional applications are United States Provisional Application Serial No. 60/005,164 filed Oct. 13, 1995 and 60/010,614 filed Feb. 2, 1996. Both of these provisional applications contained written description and drawings which are fully enabling of independent claim 53. Thus, independent claim 53 is entitled to the benefit of the October 13, 1995 filing date. Accordingly, Lary et al., which was filed on October 3, 1996, does not constitute prior art to independent claim 53. On this basis, withdrawal of the stated rejection over Lary et al. is requested.

Applicant further argues that the shaft of Makower is rigid.

As the Examiner will note, the Makower et al. device has a rigid shaft 36 that is advanced into the urethra in contrast to a flexible catheter body that is advanceable through the vasculature as recited in amended claim 53. Also, the cannula (12) of Makower et al. is advanced through a curved projection on the distal end of the shaft 36 and into the prostate, not through an opening in the side wall of a flexible catheter body as recited in amended claim 53. Nothing in Makower et al. describes or suggests any motivation to modify the rigid shaft 36 to make it flexible and capable of being advanced through the vasculature, nor does anything in Makower et al. describe or suggest any motivation to redesign the disclosed device such that the cannula would exit through a side opening in a flexible catheter body rather than through the curved projection on the distal end of the rigid shaft 36, as shown. Thus, Applicant respectfully submits that independent claim 53, as presently amended, also distinguishes over Makower et al. when taken alone or in combination with any other prior art of record.

However on pages 2 and 11of the publication, Makower states that the cannula is at least partially flexible.

With respect to the side opening of the shaft, applicant's attention is directed to figure 11 of the publication.



Page 17 of the publication describes the opening to be in the shaft to access the walls of urethral walls.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claim 53 is rejected under 35 U.S.C. 102(e) as being anticipated by Lary et al [5800450].

Lary et al discloses a system [10] that is useable to guide the advancement of a guidewire [40] from a location within the lumen of a blood vessel to a location within or outside of the wall of that blood vessel, said system comprising: a elongate catheter body [12] that is advanceable into said blood vessel lumen, said catheter body having at least one lumen extending longitudinally therethrough; an opening formed in said catheter body; a tissue penetrating element [14] having a lumen, a tissue penetrating distal tip and a distal end opening, said tissue penetrating element being altemately disposable in; a) a first position wherein the tissue penetrating element is substantially within the catheter body; and b) a second position wherein the tissue penetrating element assumes a predetermined curved configuration and extends out of the opening so as to penetrate a wall of the blood vessel adjacent to the blood vessel lumen in which the catheter is positioned wherein the guidewire is advanceable through the

lumen of the tissue penetrating element while the tissue penetrating element is in the second position.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 52-58,61-63 are rejected under 35 U.S.C. 103(a) as being unpatentable over Makower [WO 93/15664] in view of Murphy Chutorian [5891133].

Makower discloses a system [10] that is useable to guide the advancement of a guidewire [20] from a location within the lumen of a blood vessel to a location within or outside of the wall of that blood vessel, said system comprising: a elongate catheter body [30] that is advanceable into said blood vessel lumen, said catheter body having at least one lumen extending longitudinally therethrough; an opening [108] formed in said catheter body; a tissue penetrating element [20] having a lumen, a tissue penetrating distal tip and a distal end opening, said tissue penetrating element being altemately disposable in; a) a first position wherein the tissue penetrating element is substantially within the catheter body; and b) a second position wherein the tissue penetrating element assumes a predetermined curved configuration and extends out of the opening

so as to penetrate a wall of the blood vessel adjacent to the blood vessel lumen in which the catheter is positioned.

Makower does not clearly disclose a guidewire that is advanceable through the lumen of the tissue penetrating element while the tissue penetrating element is in the second position however the laser element may be replaced with other elements such as a separate stylet or hollow needle (see page 14, 3rd paragraph). Murphy-Chutorian teaches the combination of a fiber optic/guidewire bundle that is used for laser assisted TMR procedures. To replace the fiber of Makower with the fiber/guidewire bundle of Murphy-Chutorian to obtain better control of the placement of the fiber with respect to the predetermined tissue site would have been obvious to one with ordinary skill in the art at the time of the invention thereof. Makower as modified would yield a system that meets the claimed limitations.

Claim 54, see anchoring member [locking member 16] of Makower

Claim 55, see page 12, 1st paragraph of Makower.

Claims 56,57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Makower [WO 93/15664]) in view of Abele (6010480).

Examiner has applied Abele et al as a secondary teaching for increasing the frictional surface of a balloon catheter for increasing the engaging forces of the balloon to an adjacent luminal structure. It would have been obvious to one with ordinary skill in the ad to provide the outer surface of the balloon with frictional components to increase the engaging forces of the outer surface of the balloon to adiacent luminal structures.

Claims 61-63 are rejected under 35 U.S.C. 1O3(a) as being unpatentable over Makower [WO 93/15664]) in view of Edwards et al [5366490] and Shturman (5331947).

While it is not clear how Makower combines the ultrasound imaging in combination with the system [10], an imaging device comprising an anchoring member (30,32) being deployable when the catheter body is inserted into an anatomical lumen such that a surface of the balloon anchoring member will engage a wall of the anatomical lumen thereby preventing at least a portion of the catheter body from undergoing substantial movement within the anatomical lumen is taught by Edwards et al.. Shturman teaches placement of the ultrasound transducer internal to the lumen for imaging the same. If not inherent in Makower to place the imaging device internally of the lumen along with the combination of a balloon anchor/imagining means, so that the surgeon can precisely place and anchor the probe at the predetermined/selected location in viyo would have been obvious to one with ordinary skill in the ad at the time of the invention thereof. Precise location and anchoring the probe to that location offers the surgeon better means for obtaining clear imaging resolution of the selected location.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DAVID J. ISABELLA whose telephone number is 571-272-4749. The examiner can normally be reached on MONDAY-FRIDAY.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, CORRINE MCDERMOTT can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

DAVID J ISABELLA
Primary Examiner
Art Unit 3738

DJI
9/30/2006